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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,629	11/08/1999	STEVEN L. STICE	000270-086	5462

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

File

Advisory Action

Application No.	Applicant(s)
09/435,629	Stice, S. et al.
Examiner	**Art Unit**
Joseph Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Feb 12, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *Nov 12, 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: *91-120*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s).

10. ☐ Other:

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800
1630

Section 5(c):

With respect to the New Matter rejection matter under 35 U.S.C. 112, first paragraph, Applicants argue that the claimed invention is described numerous times in the specification. For support Applicants point to methods describing the transfection of CICM cells with a selectable marker *in vitro* and selecting cells transgenic cells (pages 3-4). Applicants argue that 'persons skilled in the art know that the cells that are exposed to heterologous DNA comprising a transgene may fail to express the transgene' (page 4), and that the specification 'expressly describes making the claimed invention (page 4). Applicants' arguments have been fully considered, but not found persuasive see (pages 3-5).

Initially, it is noted there is no literal support in the specification for the instant claims. Turning to the figurative support pointed to by Applicants, it is noted that neither at the specific citations nor anywhere else in the specification do any of the methods indicate making the instantly claimed composition. To the contrary the methods are directed to making CICM cells comprising heterologous DNA. For example, the method at pages 11-12 states (vi) inserting heterologous DNA into said CICM cells; (vii) selecting for transgenic CICM cells and similar method steps generally set forth at page 19. In neither case is there an indication that the instantly claimed composition is being generated, rather only CICM cells containing a transgene. The original elected claims were directed to a composition comprising CICM cells from two genetic complements to provide a chimeric embryo (claim 79). The method pointed to by Applicants in the specification provides introducing CICM cells, with or without a transgene,

into an embryo to form a chimeric embryo. In each case, the specification provides no support for generating or using the instantly claimed composition. This instant situation is analogous to *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) where under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention. (In Gentry Gallery, the "court's determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element--the control means' --as the only possible location' and that variations were outside the stated purpose of the invention.' *Gentry Gallery*, 134 F.3d at 1479, 45 USPQ2d at 1503. In the instant case, while *in vitro* transfection methods may result is some cells receiving and expression a heterologous polynucleotide and some cells not expressing the transgene, there is no clear indication that the instantly claimed invention was specifically contemplated anywhere in the instant specification. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case the specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. Further, relying on inherent properties of an intermediate product which may result from

practicing a method described in the specification fails to demonstrate that Applicants' contemplated or were in possession of the instantly claimed composition of cells.

Therefore, for the reasons above and of record, the rejection is maintained.

With respect to rejections matter under 35 U.S.C. 112, second paragraph, Applicants argue that the meaning of claim 91 is clear to persons skilled in the art. Applicants note the premise of the invention and argue that one of skill in the art would know that two different cells one expressing a transgene and one not expressing a transgene are comprised by the claim (see pages 5-6). Applicants' arguments have been fully considered but not found persuasive. The claims are not directed to a product by process, and because the same CICM cell line is required for both the CICM cell line that expresses a transgene and on that does not express a transgene, the claims fail to clearly indicate how a single cell can comprise at least two different properties.

Therefore, for the reasons above and of record, the rejection is maintained.

With respect to the rejections made under 35 U.S.C. 102(e) Applicants argue that Sims *et al.* fail to enable the claimed invention because using the methods described by Sims *et al.* the cells would not be totipotent, specifically noting that Sims *et al.* expressly state that ES cells cultured on feeder cells differentiated into epithelial (see pages 6-7 and Sims column 14, lines 44-56). Applicants' arguments have been fully considered but not found persuasive. Initially, a reading of Sims *et al.* at column 14, lines 44-56 does indicate that ES cells can differentiate into

endothelial cells, however Sims *et al.* clearly note this and indicate specific conditions for preventing differentiation of the cells in culture (lines 50-51 see also column 6, lines 60-65). Sims *et al.* teach a method for isolating ICM cells and using the cells to generate a bovine animal (claim 1). Additionally, to generate a transgenic bovine animal, Sims *et al.* teach that one can introduce a transgene into the ICM cells of step (b) (claim 6). In providing cells with a transgene Sims *et al.* teach that one can use selectable markers conventional in the art (column 13, lines 9-43).

Therefore, for the reasons above and of record, the rejection is maintained.

With respect to the rejections made under 35 U.S.C. 103 Applicants argue that Sims *et al.* fail to enable the claimed invention because using the methods described by Sims *et al.* the cells would not be totipotent, specifically noting that Sims *et al.* expressly state that ES cells cultured on feeder cells differentiated into epithelial (see page 8). Deboer *et al.* and Stewart *et al.* fail to remedy the deficiency of Sims *et al.* Applicants' arguments have been fully considered but not found persuasive. As noted above, Sims *et al.* clearly note this and indicate specific conditions for preventing differentiation of the cells in culture (lines 50-51 see also column 6, lines 60-65). Sims *et al.* teach a method for isolating ICM cells and using the cells to generate a bovine animal (claim 1). Additionally, to generate a transgenic bovine animal, Sims *et al.* teach that one can introduce a transgene into the ICM cells of step (b) (claim 6). In providing cells with a transgene Sims *et al.* teach that one can use selectable markers conventional in the art (column 13, lines 9-

43). Deboer *et al.* and Stewart *et al.* are relied upon to teach obvious embodiments which were known at the time of filing.

Therefore, for the reasons above and of record, the rejection is maintained.

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